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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,339	01/26/2004	Shawn R. Feaster	034047.003.1 (00-23)	7108

53502 7590 03/29/2007
OFFICE OF THE STAFF JUDGE ADVOCATE (SKS)
U.S. ARMY MED. RESEARCH & MATERIAL COMMAND
504 SCOTT STREET
ATTN: MCMR-JA (MS. ELIZABETH ARWINE)
FORT DETRICK, MD 21702-5012

EXAMINER

SHEN, BIN

ART UNIT	PAPER NUMBER
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1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary**Application No.**

10/763,339

Applicant(s)

FEASTER ET AL.

Examiner

Bin Shen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-36 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 31-34, 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29,30,35 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment received 2/16/2007 has been entered and claims 29-36, 39 are currently pending, claims 31-34, 36 are withdrawn from consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorette et al. (Applied Biochemistry and Biotechnology 1998;74:1-12).

Dorette et al. teach an enzyme biosensor (read as a device) for the determination of cholinesterase on polymer membrane (see abstract). The biosensor uses physical entrapment strategies (same function as a sealed chamber, see page 2, line 11-14) to co-immobilize acetylcholinesterase/choline oxidase (AChE/ChO) or butyrylcholinesterase/ChO (BChE/ChO), and it detects activities/concentrations of different substrates (read on as a plurality of proteins, see page 2, 7th paragraph). The sensitivity for each substrate and for each protein is determined by measuring the reaction rates at different concentrations through calculating a linear relationships (see Fig. 1, Fig. 3 and Table 1).

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Therefore, the cited reference is deemed to anticipate the instant claims above.

Applicant's arguments filed 11/22/2006 have been fully considered but they are not persuasive.

Applicants argue that Dorette does not anticipate the claimed invention because the device 1) requires the use of immobilized proteins, 2) requires the addition of choline oxidase, 3) measures H_2O_2 as the indicator of protein amount, 4) measures the activity of each protein using only one substrate and no inhibitor, and 5) must separately assay each protein in a sample with different sensors.

It is the examiner's position that applicant's arguments that the present invention does not require the immobilization of protein, does not require the addition of choline oxidase are not presented in the claim. In claim 29, "measuring reaction rates..." can be achieved by measuring the H_2O_2 (page 5, 4th full paragraph). Dorette also teaches that AChE and BChE are widely used for the construction of various biosensing devices monitoring the decrease of enzyme activity in the presence of inhibitors (page 2, end of 4th paragraph). "various biosensing devices" can inherently be used to assay more than one protein (enzyme). It should also be pointed out that the "sensitivity coefficient" is determining (not measured) in the claim "from the calculated linear relationships", and in Dorette, "sensitivity" is also obtained from the calculated linear relationships (page 7, 3rd and 4th paragraph, and Table 1).

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29, 30, 35, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorette et al. in view of Magnotti et al. (Clinica Chimica Acta, 1988;315:315-332), and further in view of Ellman et al. (Biochemical Pharmacology 1961;7:88-95).

Dorette et al. teach what is above.

Dorette et al. do not teach use of a handheld device with a cartridge to detect cholinesterase.

Magnotti et al. teach the reagents (see pages 317-318) needed for the testing device and the advantages to develop a portable and convenient device/kit (read on as handheld) with stable, premixed reagents (read on as cartridge) to measure cholinesterases in a field assay (see abstract and also page 329, 3rd full paragraph) because field monitoring erythrocyte and plasma cholinesterase activities is beneficial to agricultural workers and others at risk for pesticide exposure (see page 331, 2nd full paragraph).

Ellman et al. teach a new and rapid colorimetric determination of acetylcholinesterase activity which is later developed into the Test-Mate OP kit by EQM Research Inc., Cincinnati, OH, USA (as stated on page 1078, lines 11-14 of Paz-

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y-Mino et al. Environmental Health Perspectives 2002;110:(1077-1080)).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to develop a handheld device with a biosensor (as taught by Dorette et al.) and a cartridge (whose convenience is suggested by Magnotti et al.) to monitor enzyme activity because Dorette et al. teach a biosensor to detect enzyme activity, and Magnotti et al. teach the reagents that are needed for the enzyme assay and suggest to develop a portable and convenient device to monitor cholinesterases activity in the field. One would have been motivated to make the modification because Magnotti define the optimal criteria for field measurement of cholinesterase (see page 328, 1st paragraph of Discussion) and the need for a portable/handheld device/kit with stable, premixed reagents (cartridge), and would reasonably have expected success because Dorette et al. teach how to make a biosensor for cholinesterase detection, and Magnotti et al. teach many advantages of developing a portable, convenient and stable assay system to be used in the field.

The Test-Mate OP system has all the components that are required for the detection of cholinesterase as described by Ellman et al., thus it would have been obvious to one of ordinary skill in the art to use the Test-Mate OP kit to detect, measure or monitor the activities or concentrations of cholinesterase instead of the claimed device.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to

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one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed 11/22/2006 have been fully considered but they are not persuasive.

Applicants argue that Doretta does not anticipate the claimed invention because the device 1) requires the use of immobilized proteins, 2) requires the addition of choline oxidase, 3) measures H_2O_2 as the indicator of protein amount, 4) measures the activity of each protein using only one substrate and no inhibitor, and 5) must separately assay each protein in a sample with different sensors.

It is the examiner's position that applicant's arguments that the present invention does not require the immobilization of protein, does not require the addition of choline oxidase are not presented in the claim. In claim 29, "measuring reaction rates..." can be achieved by measuring the H_2O_2 (page 5, 4th full paragraph). Doretta also teaches that AChE and BchE are widely used for the construction of various biosensing devices monitoring the decrease of enzyme activity in the presence of inhibitors (page 2, end of 4th paragraph). "various biosensing devices" can inherently be used to assay more than one protein (enzyme). It should also be pointed out that the "sensitivity coefficient" is determining (not measured) in the claim "from the calculated linear relationships", and in Doretta, "sensitivity" is also obtained from the calculated linear relationships (page 7, 3rd and 4th paragraph, and Table 1). The Test-Mate OP system has all the components that are required for the detection of cholinesterase as described by Ellman et al.,

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thus it would have been obvious to one of ordinary skill in the art to use the Test-Mate OP kit to detect, measure or monitor the activities or concentrations of cholinesterase instead of the claimed device.

Conclusion

No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify

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Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey can be reached at (571) 272-0775.

B Shen

Art Unit 1655

Ralph Gitomer

RALPH GITOMER
PRIMARY EXAMINER
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